Kansas State Board of Pharmacy Minutes of the July 24 & 25 2014 Board Meeting

800 SW Jackson, Lower Level KBOHA Conference Room Topeka, KS 66612

Thursday, July 24, 2014

Meeting Called to Order: President David Schoech called the meeting to order at 9:04am.

Members Present: David Schoech, R.Ph., President; Bob Haneke, Pharm D., Vice President; Jim Garrelts, Pharm. D.; Michael Lonergan, RPh.; Cheri Pugh, Public Member; Chad Ullom, R.Ph., Investigative Member; and John Worden, Pharm. D. (Arrived 9:26am).

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Reyne Kenton, Compliance Inspector; Melissa Martin, Compliance Inspector; Marty Singleton, PDMP Director; and Randall Forbes, General Counsel.

Others Present: Zane Hoffman, Pharmacy Intern; Adam Blaes, Pharmacy Student; and for others – see attached listing.

Approval of the Agenda:

A motion was made and seconded to approve the agenda as printed. (Haneke/Ullom) Motion passed.

A motion was made and seconded to add "Approval of Contract with KPhA/KsPRN" Ullom/Haneke. Motion passed.

Approval of the April 24 & 25, 2014 Minutes:

A motion was made and seconded to approve the minutes from April 24 & 25, 2014 as printed. (Garrelts/Ullom) Motion passed.

Board Discussion, Action, and Reports

Review of Cardinal Health Care Pharmacist Waiver – Cardinal Health – Martha Russell, Assistant General Counsel; Robert Mitchell RPh.BNCP; Jimmy Phan, Site supervisor; and Sean Waters, VP Chemical/Pharmaceutical Operations came to request an extension for the current waiver of a pharmacist for a nuclear drug manufacturer pursuant to K.S.A. 65-1643. The Board reviewed the technical training and experience of those performing duties of supervision. A motion was made and seconded to extend the waiver with the requirement that Cardinal must notify the Board in writing of any change in the Site Supervisor. (Garrelts/Haneke) Motion passed.

<u>Budget</u> – Ms. Yingling presented the current numbers of the Board of Pharmacy fee fund. The Board used the entire appropriation for FY2014 by expending any remaining money on needed equipment for the office. Ms. Yingling gave information on revenue sources for the past several years. Money was expended from the litigation fund this year in the amount of approximately \$20,000. The decrease in fees will begin in September and will reduce the agency cash balance.

Mr. Worden arrived 9:26a.m.

Integrity Monitoring presented by Affiliated Monitoring, Inc. – Wendy Anderson,RPh, Compliance Analyst with Affiliated Monitoring, Inc. made the presentation on behalf of AMI. AMI provides independent monitoring of professionals and their compliance with the laws and regulations. The monitoring allows the licensee or registrant to remain in business while coming into compliance with requirements of the Board. The cost is borne by the licensee or registrant. AMI can monitor licensees or registrants in other states if the Board makes monitoring a requirement to maintain the license or registration in Kansas. The monitoring would need to be placed in the stipulation or final agency order with the registrant understanding they would be paying the cost. Cost is approximately \$300 per hour. A monitoring inspection would range between 2 – 4 hours. AMI tries to be specific to the problem and not spend time looking at non-problems. AMI supplies the name and credentials of the monitor to the Board so the Board is assured the monitor can provide the needed service. The Board thanked Ms. Anderson for her presentation and discussed potential use of the service as a tool for disciplinary cases.

President Schoech welcomed Senator Vicki Schmidt to the meeting.

Approval of Contract with KPhA/KsPRN –Ms. Billingsley presented the contract for Board consideration covering the period from July 1, 2014 through June 30, 2017. There was no fee increase requested. A motion was made and seconded to approve the contract as presented. (Haneke/Worden) Motion passed.

Approval of New Pharmacists and New Registrants

A motion was made and seconded to approve the new licenses and registrations. (Ullom/Worden) Motion passed.

<u>NPLEx Report</u> – Ms. Billingsley provided the information. There have been very few problems. Southeast Kansas cities, Pittsburg the latest, are continuing to restrict purchasing over-the-counter pseudoephedrine (PSE) to prescription only. None of the cities have contacted the Board office regarding issues with PSE or requested changes in the law.

<u>KTRACS</u>– Mr. Singleton provided the update. The second quarter threshold report has been processed. The top "diverter"/patient saw 46 prescribers and 27 dispensers and he has been in the top 20 diverters for the last four quarters. KTRACS is increasing the numbers of professionals accessing the information. The number of inquiries through PMPi is increasing. There is an advisory committee meeting next Friday, August 1. Pharmacy/Submitter's compliance shows:

110 have never reported.

- 36 have no current DEA number
- 58 are 100+ days delinquent
- 39 are 11-100 days delinquent
- 33 are 5-10 days delinquent
- 2 are 4 days delinquent
- 52 are 3 days delinquent
- 60 are 2 days delinquent

Letters will be sent out inquiring as to the reason for noncompliance. These letters will be sent in a staggered fashion so the office and Appriss is not flooded with calls at the same time.

Other updates included current status of programs with LACIE, KHIN, Kroger, SAMHSA, and Harold Rogers. The annual meeting of NASCSA is in October.

Renewal of Licenses and Registrations – Mr. Singleton gave an update on office activity. The training manual is almost complete. The current renewal period had a small change in question regarding discipline. Approximately 93% of all renewals have been completed. 455 licenses/registrations have not been renewed as of yet (does not include retail dealers and technicians).

Post audit has requested the Board have a security assessment completed by an independent source before December 2015 regarding the Board's IT security. New servers have been purchased for increased capacity and due to aging out of the old servers.

Recess: Mr. Schoech declared a break at 10:55am to reconvene in 20 minutes.

Reconvene: Mr. Schoech reconvened the meeting at 11:15am

NABP Items

- Comments regarding Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction – Letter from NABP to CMS
- Comments to SAMHSA regarding Privacy Regulations related to confidentiality of alcohol and drug abuse patient records – Questions regarding regulations and how they may interfere with PDMPs.
- Interactive Member Forum December 2 & 3, 2014 Board Member Forum Robert Haneke plans to attend as the Board's representative.

Board Member Reports

- NABP Annual Meeting Resolutions Chad Ullom reported on the resolutions from the annual meeting. There were eight total resolutions including: Illegal Importation of Drugs, Veterinary Medications, connection to PMPi, selling of tobacco products, and strategies for preventing pharmacy robberies and thefts.
- Continuing Education for Pharmacists Mr. Ullom told the Board of the Oregon online continuing education on prescription error reduction. The CE is 18 hours and could be used as a disciplinary tool with the advantage the pharmacists may learn how to prevent errors.
- Educational Video for Pharmacists that addresses Prescription Drug Abuse –
 NABP put together a video stressing all pharmacists look for warning signs of

prescription drug abuse. NABP used the pharmacy board executives to introduce the video. The video is accessible from the Board website. There is a push for states to become stricter in discipline of pharmacists when there is diversion.

The next NABP national meeting will be in New Orleans in May 2015.

Bob Haneke – reported on the continuing education requests his committee has been receiving. The committee is comprised of Joan Kramer, Barb Woods, John Funk, and himself. He requested an article be placed in the newsletter about how CE is approved and when the information must be presented to be considered for approval.

Michael Lonergan – reported on a conversation with John Foust about NABP's verified pharmacy program. The costs of the program are borne on the licensee/registrant. Mr. Lonergan talked about District 6 and his desire to run for executive committee member.

Cheri Pugh – thanked the Board for pharmacies dedication to providing care for patients. She said pharmacy never hears the good they do only the problems.

John Worden – reported the National Rural Health Association is supporting pharmacists as a health provider. The Rural Health Clinic and Critical Access Hospital will be in Kansas City September 30 through October 3.

Executive Director Report

- District 6 Meeting 2015 Kansas Hosting. Ms. Billingsley will coordinate with KU in location, date and meeting duties. Kansas will recommend that the meeting be held in Lawrence in September or October.
- Mike Lonergan has signed up to run for the District 6 position. A motion was made and seconded to endorse Mike Lonergan for District 6 Executive Committee Representative (Ullom/Worden) Motion passed.
- Walgreens Well Experience Model HHS says the model is okay and does not present a violation of HIPAA.
- Health Workforce Partnership Committee is looking for ways to collect workforce demographics. Ms. Billingsley said much of the information will not be needed or used by the pharmacy board and questions whether pharmacists will voluntarily give information that is not statutorily required. The committee discussed possibly holding the release of a renewal until the survey had been completed. The Board suggested Dr. Moser come to the Board and explain the type of information requested, how it would be used, and if the collectors planned to sell the information to another group.
- Dr. Moser convened a group of stakeholders to address the concerns of Zohydro and other controlled substances. He does not consider this a statewide health emergency situation. KTRACS statistics show no prescriptions were filled in the first quarter of 2014 and only 15 in the second. Dr. Moser would rather the state address the over prescribing and use or misuse of all pain medications proactively.
- Joint Policy Statement on Pain Management The Board of Pharmacy, Board of Healing Arts, and Nursing Board have been updating the policy statement. Dr.

Twillman is working on the last revision so that each Board can review and approve.

• KPhA will meet in Overland Park in September 2015 as a joint meeting with Missouri and Oklahoma.

Staff Reports

Jim Kinderknecht – thanked the Board for the opportunity to attend NABP Annual Meeting in Phoenix this year. Mr. Kinderknecht said the Oregon material on errors should be used to change the behavior of errors in the pharmacy.

Reyne Kenton – thanked Ms. Billingsley for the bad weather updates she sends to the inspectors while traveling. They are used to make travel adjustments for safety. Ms. Kenton reported on the roundtable between the staffs of the Board of Healing Arts, Board of Nursing, KBI, DEA, and the Board of Pharmacy. The group met in an effort to improve collaboration and use resources more efficiently.

Carly Haynes – reported on the webinar concerning hazardous drugs and how the USP <800> may affect every pharmacy. She also reported on a date variation between actually taking a CE and the CE appearing on the CPE monitor. Ms. Haynes informed the Board she had attended an NABP VPP survey of a Kansas pharmacy. The survey, depending on services provided by the pharmacy, can be either 24 or 48 pages long with the longest taking a minimum of 5 hours to complete.

Recess: Mr. Schoech recessed the meeting at 12:16pm for lunch to reconvene at 1:00pm.

Reconvene: Mr. Schoech reconvened the meeting at 1:10pm.

Election of Officers

President – A nomination was made and seconded to elect Robert Haneke as president. (Schoech/Ullom) There were no other nominations. Mr. Haneke was unanimously elected as president.

Vice-President – A nomination was made and seconded to elect Chad Ullom as vice president. (Haneke/Lonergan) There were no other nominations. Mr. Ullom was unanimously elected as vice-president.

Investigative Member – A nomination was made and seconded to elect Mike Lonergan as investigative Member. (Schoech/Worden) Motion passed. After Board discussion of necessity – A nomination was made and seconded to elect John Worden as alternate Investigative Member. (Haneke/Lonergan) Mr. Lonergan and Mr. Worden were elected unanimously.

Dr. Haneke thanked the Board for electing him as president.

Members Present: Bob Haneke, Pharm D., President; Chad Ullom, R.Ph., Vice President; Michael Lonergan, RPh., Investigative Member; John Worden, Pharm. D. Alternate Investigative Member; Jim Garrelts, Pharm. D.; Cheri Pugh, Public Member; and David Schoech, R.Ph.

Reports

<u>Collaborative Practice Advisory Committee</u> – Dr. Haneke opened the topic for discussion. A motion was made and seconded to appoint Dr. Garrelts as chairman of the committee. (Worden/Ullom)

The Board reviewed the applications for membership. Two of the pharmacists must have collaborative practice experience and one can have no related experience. Dr. Garrelts abstained from voting for members as some applicants work for Via Christi. A motion was made and seconded to appoint Lyndsey Hogg, Tiffany Shin and Rick Couldry. (Schoech/Worden) Both motions passed.

A motion was made and seconded to set the length of terms as:

- Jim Garrelts 2 years
- Lyndsey Hogg 2 year
- Tiffany Shin 1 year
- Rick Couldry 1 year.

(Worden/Ullom) Motion passed.

The Board discussed the ground rules and direction the committee should go. Dr. Worden asked who will verify or oversee the pharmacists that participate in collaborative agreements. Dr. Haneke read the questions that have been collected regarding collaborative practice. The regulations that will be drafted will fall under the Board of Pharmacy. Dr. Garrelts requested any other question be sent to him for the committee to discuss.

<u>Automation Regulations</u> – The Board discussed the proposed regulations. They gave Ms. Billingsley suggestions for language revisions.

Pharmacy Technician Training – Mr. Schoech reported on the meeting discussing the formation of a committee and the drafting of regulations. Their proposal was to form an advisory committee of nine stakeholders with one of those as the committee chairperson. All stakeholders could submit options but the committee would be responsible for drafting the regulations as a recommendation to the Board. The task force gave their recommendations to be used by the advisory committee. David Schoech would like to volunteer serve on the committee. He recommended Lindsey Massey, Mike Larkin, Beth Riley, and to find representation from other organizations to total nine members. Mr. Schoech will serve as chairperson and recruit the rest of the committee. A meeting will be scheduled as soon as the committee members are identified and agree to serve.

Recess: Dr. Haneke declared a break at 2:55pm to reconvene in 20 minutes. **Reconvene:** Dr. Haneke reconvened the meeting at 3:15pm

<u>Drug Supply Chain Security</u> – Ms. Billingsley attached the information to the agenda. Mr. Forbes was requested to review the language. Mr. Forbes discussed the conflict between the federal law and Kansas law. The federal law changed recently to cause the conflict. The states now have to reassess their laws and how they will need to change their laws to be able to control what drugs enter their state. Ms. Billingsley reported Kansas currently has 1000+ distributors. Kansas registers every distributor or third party logistics supplier that ships, owns or sells drugs in or into the state. Mr. Forbes suggested the Board wait until the federal regulations are drafted/proposed or

enacted. He did suggest the Board change the statute language to require third party logistic suppliers to the registered.

ACPE Approved Immunization Programs – Ms. Billingsley told the Board that ACPE does not approve the immunization courses presented by KU School of Pharmacy. Nor do they approve OU or SWOSU schools either. The students do not have an ACPE approved immunization certificate. ACPE does accredit schools of pharmacies and does accredit providers wishing to approve continuing education. When KU dropped the ACPE continuing education provider status, the course they had on immunizations was no longer ACPE approved. Many states require ACPE certification only, so now the KU, OU, SWOSU, and some other students do not have ACPE approved immunization course. For students that graduate from KU and stay within the state it is no problem since the Board allowed ACPE or a Board approved course. The Board approved KU's course. Recent KU pharmacists leaving the state may need to retake an ACPE approved course. There are no continuing education requirements for continuing to perform immunizations only maintenance of a current CPR certification. What assurance does the Board need or should they require proving the courses given to the students were sufficient to protect Kansas consumers/patients? The Board will continue to study the issue and possible resolutions.

<u>Theft Reporting Regulation</u> – Ms. Billingsley discussed in which regulation the reporting would be placed. The logical regulation was verbatim to the federal regulation but addresses the actions of prescribers as well as pharmacists so the Attorney General's Office cannot approve unless changes are made to a majority of the regulation.

Investigative Member Report – Closed Cases – Mr. Ullom presented the closed cases and asked for any questions. There were no questions

Executive Session:

Attorney Client---

A motion was made and seconded to enter into executive session at 4:10pm for 10 minutes with the Board's attorney pursuant to K.S.A. 75-4319(b)(2) to discuss privileged information deemed to be in the attorney client relationship to include Randy Forbes, Board Counsel; and Executive Secretary, Debra Billingsley. (Worden/Pugh) Motion passed.

Dr. Haneke reconvened the meeting at 4:21pm.

Adjourn: Dr. Haneke adjourned the meeting at 4:21pm.

Friday, July 25, 2014

Meeting Called to Order: President Haneke called the meeting to order at 9:00am. Dr. Haneke requested for anyone in the audience to sign the attendance sheet.

Members Present: Bob Haneke, Pharm D., President; Chad Ullom, R.Ph., Vice President; Michael Lonergan, RPh, Investigative Member; John Worden, Pharm. D.

Alternate Investigative Member; Jim Garrelts, Pharm. D.; Cheri Pugh, Public Member; and David Schoech, R.Ph.

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Inspector; Reyne Kenton, Compliance Inspector; Marty Singleton, Assistant Director; and Randall Forbes, General Counsel.

Others Present: Zane Hoffman, Pharmacy Intern; Adam Blaes, Pharmacy Student; and for others – see attached listing.

Administrative Proceedings

- Steven Doane, R.Ph. (1-15069) Case 14-06 Steven Doane was present without counsel. Mr. Forbes presented the information to the Board. A motion was made and seconded to enter into executive session for 5 minutes to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include: Steven Doane, Randy Forbes, Debra Billingsley, the KsPRN representatives(Vicki Whitaker, Mike Larkin, and Ralph Holbrook) and to return to open session at 9:10a.m. (Garrelts/Worden) Motion passed. Dr. Haneke reconvened the meeting at 9:10am. A motion was made and seconded to accept the Stipulation and Final Agency Order with Mr. Doane (Worden/Garrelts) Motion passed.
- Ankeyta White, Pharmacy Technician Case 14-21 The case has been continued until the October meeting in Wichita.
- Sharon Griffiths, Pharmacy Technician (number) Case 14-50 Sharon Griffiths was not present. Mr. Forbes presented the case to the Board. A motion was made and seconded to accept the Final Agency Order to revoke the pharmacy technician registration of Sharon Griffiths (Schoech/Worden) Motion passed.
- Lynn T. Nguyen, Pharmacy Technician (number) Case 14-44 Lynn T Nguyen was not present. Mr. Forbes presented the case to the Board. A motion was made and seconded to accept the Final Agency Order to revoke the pharmacy technician registration of Lynn T. Nguyen (Garrelts/Worden) Motion passed.
- Chris Henington, R.Ph. (1-13153) Case 14-55 Chris Henington was present with counsel, Randy Debenham. Mr. Forbes presented the information to the Board. A motion was made and seconded to enter into executive session at 9:35am for 10 minutes to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include: Chris Henington and counsel, Randy Forbes, Debra Billingsley, the KsPRN representatives(Vicki Whitaker, Mike Larkin, and Ralph Holbrook) and to return to open session at 9:45a.m. (Worden/Lonergan) Motion passed. Dr. Haneke reconvened the meeting at 9:47a.m. A motion was made and seconded to extend the executive session as above for 20 minutes and to reconvene at 10:07am (Schoech/Worden) Motion passed. Dr. Haneke reconvened the meeting at 10:07am. Mr. Forbes recommended the Board take no action at this time and to continue at the October Board meeting. The license will remain suspended. Mr. Ullom told Mr. Henington that he was glad he has taken ownership of his problem but must follow

through with KsPRN. Dr. Garrelts told Mr. Henington the Board will be watching actions not words. Mr. Henington will be placed on the October Board case docket.

Recess: Dr. Haneke declared a break at10:08am to reconvene in 15 minutes. Reconvene: Dr. Haneke reconvened the meeting at 10:23am

- Haley Diane Sneed, Pharmacy Technician (number) Case 14-57 Haley Diane Sneed was not present. Mr. Forbes presented the case to the Board. A motion was made and seconded to accept the Final Agency Order to revoke the pharmacy technician registration of Haley Diane Sneed (Worden/Lonergan) Motion passed.
- Bill Poulos, R.Ph. (number) Case 9-27 Bill Poulos was not present. Ms. Billingsley reported that Mr. Poulos has been released from his CIPP contract.
- Angela Little, R.Ph. (number) Case 13-132 Angela Little was not present. Mr.
 Forbes presented the information to the Board. A recommendation was received
 from KsPRN stating Ms. Little was okay to return to a dispensing function. A motion
 was made and seconded to permit Ms. Little to return to dispensing. (Schoech/Pugh)
 Motion passed.

Summary Orders

• K-Mart Pharmacy #4171 (2-09802) **Case 14-42** – K-Mart had no representation present. Ms. Billingsley presented the case and recommended the Board accept the Summary Order. A motion was made and seconded to approve the Summary Order with K-Mart Pharmacy #4171 (Schoech/Worden). Motion passed.

Meeting Dates for 2015

January – 8 & 9, 2015

February – 13 or 20th (if in person – Lawrence. Otherwise will be phone meeting)

April – 23 & 24, 2015

July - 16 & 17, 2015

November – 5 & 6, 2015

The meetings will be in Topeka or Wichita depending on availability of the dates. Three in Topeka and one in Wichita

District 6 – October 5-7 or 12-14 or 19-21 depending on availability of hotels in Lawrence.

Adjourn: Dr. Haneke adjourned the meeting at 10:58am.